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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/551,607

09/30/2005

Yasuhiko Tabata

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EXAMINER

SAOUD, CHRISTINE J

ART UNIT

PAPER NUMBER

1647

NOTIFICATION DATE

DELIVERY MODE

04/09/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/551,607	<b>Applicant(s)</b> TABATA ET AL.	
	<b>Examiner</b> Christine J. Saoud	<b>Art Unit</b> 1647	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 December 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 4, 5, 7, 10 and 13-14 (and 3, 6 in part) is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6, 8-9, 11-12, 15-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Amendment***

Claims 1, 4-5, 7, 10, and 13-14 have been amended in the response filed 28 December 2007. Claims 1-16 are pending in the instant application. Claims 4, 5, 7, 10 and 13-14 are withdrawn from consideration for the reasons provided below. Applicant has indicated claims 3 and 6 has being withdrawn, however, they are only withdrawn in part as including non-elected inventions. Lastly, Applicant has indicated that claims 8-9, 11-12 and 15-16 as being withdrawn, however, these claims read on the elected invention and are part of the Office action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Applicant's arguments filed 28 December 2007 have been fully considered but they are not deemed to be persuasive.

### ***Election/Restrictions***

Newly amended claims 4, 5, 7, 10 and 13-14 are directed to an invention that is independent or distinct from the inventions set forth in the restriction requirement mailed 21 June 2007. The original claims were all directed to compositions, while the newly amended claims are directed to methods of treatment.

The claimed invention (compositions comprising bFGF and a gelatin gel) and the newly amended claims (4, 5, 7, 10 and 13-14) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the compositions of the elected invention could be used in an entirely different method, such as in wound healing, rather than in the method of treating ischemia. While the composition claims recite an intended use, this does not convey patentable weight since the composition could be used for other things and the intended use does not place any material limitations on the composition.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 4, 5, 7, 10 and 13-14 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 3 and 6, with respect to VEGF and HGF, remain withdrawn in part from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 27 August 2007.

Claims 1-2, 8-9, 11-12, 15-16 and claims 3 and 6 with respect to bFGF are under examination in the instant Office action.

### ***Specification***

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The claims are not directed to methods of treatment because the elected invention was directed to compositions comprising gelatin hydrogel and bFGF. The title of the invention should reflect this. Correction is required.

### ***Claim Objections***

Claims 8-9, 11-12 and 15-16 remain objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Even though the preambles and/or intended uses differ, the structural and functional requirements of each claim are identical. Applicant is reminded that functional language is given no patentable weight in a product claim. The same product is being claimed multiple times. The dependent claims require no components in addition to the complex of claims 1-3 and 6. Therefore, the claims are not further limiting.

Applicant states at page 7 of the response that these claims have been withdrawn. However, this is not a proper response to the objection and the Examiner

can find no basis from which to withdraw the claims. Therefore, the objected is maintained.

With respect to claims 4-5, 7, 10 and 13-14, the amendment of these claims to methods avoids the objection to the claims. However, the claims have now been withdrawn as being directed to a non-elected invention for the reasons set forth above.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-9, 11-12 and 15-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8, 11 and 15 require the same components as claim 3 and fail to further limit the agent of claim 3.

Claims 9, 12 and 16 require the same components as claim 6 and fail to further limit the agent of claim 6.

Even though the preambles and/or intended uses differ, the structural and functional requirements of each claim are identical. Applicant is reminded that functional language is given no patentable weight in a product claim. The same product is being claimed multiple times. The dependent claims require no components in addition to the complex of the base claims. Therefore, it is unclear what material limitations are intended, if any, by the intended use language of the claims.

Applicant asserts that the claims have been withdrawn and therefore, the rejection is moot. This argument has been fully considered, but is not persuasive. There is no basis from which to withdraw the claims, therefore, the rejections stand.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 6, 8-9, 11-12 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tabata et al. (Biomaterials 20: 2169-2175, 1999) as evidenced by Wunderlich et al. and in view of Tabata (U.S. Patent Application Publication US 2004/0253294, filing date of 7/15/2002).

Tabata et al. teach gelatin hydrogels containing bFGF. The bFGF was complexed with acidic gelatin. While Tabata et al. does not specifically disclose the zeta potential of the material in aqueous solution, this property would be inherent to the complex as well as the fact that Tabata et al. uses the same acidic gelatin as the instant application. While Tabata et al. does not specifically disclose the molecular weight of the gelatin, this property is also inherent to the gelatin which was used by Tabata et al. This is evidenced by Wunderlich et al. which teach that acidic gelatin has a molecular weight of 185 kD (see table 1). Tabata et al. do not teach preparation of the hydrogel by emulsification in oil.

US 2004/0253294 teaches methods of making gelatin hydrogels which contain growth factors such as hepatocyte growth factor (HGF) and fibroblast growth factor as active agents. The gelatin used for the hydrogels has a zeta potential of about -15 to about -20 mV (see [0046]). The reference also teaches that spherical and granular gelatin hydrogels can be prepared by a method which includes emulsification in oil (see [0062] and [0067]).

It would have been obvious at the time the instant invention was made to prepare the gelatin hydrogels of Tabata et al. using the method of US 2004/0253294 because Tabata teaches that this method is useful for preparing spherical and granular gelatin hydrogels. One would have been motivated to use the methods of Tabata because the reference states that the method works well and uses the same gelatin as that of the instant claims and that of Tabata et al. Therefore, one would have a reasonable expectation of success in preparing gelatin hydrogels as claimed, absent evidence to the contrary.

Applicant argues at page 8 of the response that claim 1 recites that the gelatin hydrogel is made by emulsification in oil. Applicant's argument has been fully considered, but not persuasive. The new grounds of rejection reflect this amendment to the claims.

Applicant argues at page 9 that Wunderlich is not a proper prior art reference to support the notion that the molecular weight is inherent to the claimed gelatin because Type A gelatin has a different zeta potential. Applicant's argument has been fully considered, but is not persuasive. The Examiner does not have a laboratory with which

to measure the molecular weight of gelatin. However, based on Wunderlich, it is reasonable to conclude that gelatin has a particular molecular weight, and that it would be inherent to gelatin. Applicant has offered no evidence which shows that the gelatin of Tabata et al. has a different molecular weight than the gelatin used in the instant invention. Regardless, Tabata appears to use the same gelatin (based on the same zeta potential), so this argument is moot considering it also would have been obvious to use the gelatin of Tabata as well as the methods of preparing the gelatin hydrogel (using oil emulsion). Therefore, the invention as a whole would have been prima facie obvious at the time it was made, absent evidence to the contrary.

### ***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on Monday-Friday, 6AM-2PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christine J Saoud/

Primary Examiner, Art Unit 1647